



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE  
NATIONAL INSTITUTES OF HEALTH

FOR US POSTAL SERVICE DELIVERY:

Office of Laboratory Animal Welfare  
6700B Rockledge Drive, Suite 2500, MSC 6910  
Bethesda, Maryland 20892-6910  
Home Page: <http://grants.nih.gov/grants/olaw/olaw.htm>

FOR EXPRESS MAIL:

Office of Laboratory Animal Welfare  
6700B Rockledge Drive, Suite 2500  
Bethesda, Maryland 20817  
Telephone: (301) 496-7163  
Facsimile: (301) 480-3387

June 11, 2021

Re: Animal Welfare Assurance  
A3391-01 [OLAW Case 3K]

Dr. Christopher O'Byrne  
Vice President and Associate Dean  
Research Administration & Operations  
Wake Forest University  
Medical Center Boulevard  
Winston-Salem, NC 27157

Dear Dr. O'Byrne,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your May 3, 2021 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Wake Forest University. According to the information provided, OLAW understands that a member of the research team consolidated mice from different cages during euthanasia against institutional policies. This study was PHS funded.

As a corrective measure, the Attending Veterinarian (AV) retrained the research team and explained expectations in terms of compliance with proper euthanasia techniques and the AV will coordinate with the lab manager to promote compliance amongst all members of the research team.

OLAW appreciates the prompt consideration of this matter by Wake Forest University which is consistent with the philosophy of institutional self-regulation. OLAW expects continuing post-approval monitoring to prevent recurrence of this non-compliance and potential associated animal welfare concerns. Based on the information provided, OLAW is satisfied that appropriate steps have been taken to investigate this incident and to attempt to prevent recurrence. We appreciate being informed of this matter and please contact us with any further questions or concerns.

Sincerely,

Nicole L. Lukovsky-  
akhsanov -S

Digitally signed by Nicole L.  
Lukovsky-akhsanov -S  
Date: 2021.06.11 11:49:07  
-04'00'

Nicole Lukovsky-Akhsanov, DVM, MPH, DACLAM  
Division of Compliance Oversight  
Office of Laboratory Animal Welfare

cc: IACUC contact

May 3, 2021

Axel V. Wolff, M.S., D.V.M.  
Director, Division of Compliance Oversight  
Office of Laboratory Animal Welfare  
National Institutes of Health  
RKL1, Suite 1050, MSC 7982  
6705 Rockledge Drive  
Bethesda, MD 20892-7982

Re: Animal Welfare Assurance A3391-01  
Wake Forest incident number AWC21-004

Dear Dr. Wolff:

This is an official notification that the Wake Forest University (WFU) Animal Care & Use Program identified and resolved a deviation from standard procedure, which the WFU Institutional Animal Care and Use Committee (IACUC) determined must be reported to your office.

PHS funding:

The following PHS funds provided support this project: R01CA182424; R01CA193813

In accordance with federal expectations, the WF IACUC has forwarded information regarding this incident to our the WF School of Medicine sponsored research office, which will review relevant direct costs associated with the procurement, care and use of the animal(s) related to this deviation. Relevant costs will be paid from a nonfederal source, as appropriate.

Incident:

A member of the research team consolidated mice of different cages during euthanasia against institutional policies.

Preliminary Report:

No preliminary report was made to OLAW regarding this incident.

Resolution:

The IACUC approved the following actions to resolve this incident:

1. The Attending Veterinarian retrained the research team and explained expectations in terms of IACUC compliance with regard to proper euthanasia techniques.
2. The Attending Veterinarian will coordinate with the lab manager to promote compliance amongst all members of the research team.

All actions have been completed/implemented at this time, and the WFU IACUC considers this matter closed. Program oversight staff will continue to monitor animal care and use procedures to ensure compliance with IACUC approved processes.

WFU is committed to protecting the welfare of animals used in research and teaching. Please, contact (b) (6) if you have questions or comments regarding any aspect of this incident or its resolution.

Sincerely yours,

(b) (6)

Christopher O'Byrne  
Vice President & Associate Dean  
Research Administration & Operations  
Institutional Official

cc: Dr. Czoty, Chairperson, WF IACUC  
AAALAC International

## Wolff, Axel (NIH/OD) [E]

---

**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Friday, May 7, 2021 7:23 AM  
**To:** (b) (6)  
**Cc:** OLAW Division of Compliance Oversight (NIH/OD)  
**Subject:** RE: Final Report on AWC21-004 and AWC21-005

Thank you for these reports. We will send responses soon.

Axel Wolff, M.S., D.V.M.  
Deputy Director, OLAW

**From:** (b) (6)  
**Sent:** Wednesday, May 5, 2021 11:50 AM  
**To:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Cc:** (b) (6) Paul Czoty  
<pczoty@wakehealth.edu>; AAALAC International (accredit@AAALAC.org) <accredit@AAALAC.org>  
**Subject:** Final Report on AWC21-004 and AWC21-005

Please find the final report on the management of the noncompliance incidents AWC21-004 and AWC21-005 that involved the care and use of animals in research or teaching at Wake Forest University (Assurance No. D16-00248 (A3391-01)).

Please contact us with any questions or concerns.

Thank you,  
(b) (6)

(b) (6)